REMARKS

Status of the Claims

Claims 1, 2, 4, 6-14, 17-22, 24, 25, and 29-32 are currently pending in the application.

Claims 12, 20, 22, 25 and 31 are amended with entry of this amendment.

Claims 1, 2, 4, 6-14, 17-22, 24, 25, and 29-32 remain under consideration with entry of this amendment.

Summary

Claims 1, 2, 4, 6-14, 17-22, 24, 25, and 29-32 are pending in the application and were examined in the Office Action dated 15 June 2004. Applicants note with appreciation that claims 25 and 32 have been allowed, and further that claims 14, 17 and 31 are deemed allowable if amended to include all base limitations. However, the drawings have been objected to under 37 C.F.R. §1.83(a), and claims 1, 2, 4, 6-13, 18-22, 24, 29 and 30 have been rejected on the following basis: **(a)** claims 1, 2, 4, 6-13, 18-20, 22, 24 and 29 were rejected under 35 U.S.C. §102(b) as unpatentable over U.S. Patent No. 5,087,244 to Wolinsky ("Wolinsky"); **(b)** claim 30 was rejected under 35 U.S.C. §103(a) as unpatentable over Wolinsky; and **(c)** claim 21 was rejected under 35 U.S.C. §103(a) as unpatentable over Wolinsky in view of U.S. Patent No. 6,113,915 to Aoki et al. ("Aoki"). Applicants respectfully traverse the objection to the drawings and all pending claim rejections for the following reasons.

Overview of the Amendment

Applicants, by way of this amendment, have amended claims 12, 20, 22, 25 and 31 to correct certain minor typographical errors, and to recite the invention with greater specificity. More particularly, claim 12 has been amended to insert a missing word ("a"), claim 20 has been amended to remove unnecessary punctuation, claim 22 has been amended to correct its dependency to now derive from claim 20, claim 25 has been

amended to insert method step indicators, and claim 31 has been amended to insert some missing language. Support for the amendments to claims 12, 20, 22, 25 and 31 can be found throughout the specification as originally filed, and in the claims as originally presented. Accordingly, no new matter has been added by way of these amendments to claims 12, 20, 22, 25 and 31, and the entry thereof is respectfully requested.

Applicants, also by way of this amendment, have presented minor amendments to the specification to correct obvious typographical errors, and have further submitted formal drawings to replace Figures 1-9 as originally presented with the application, and to correct a minor error in Figure 6.

More particularly, paragraph [00133] has been amended to correct minor typographical errors appearing in the original text. In particular, the flow out of the devices in each of the drawings should have been referred to as reference number 70b as can be seen in each of the drawings 1-5, 7 and 8. In addition, the second portion of the internal flow pathway depicted in Figure 6 should have been referred to as reference number 70a'. Finally, the drawing that was referred to should have been Figure 6, instead of Figure 7. Applicants have included a replacement paragraph [00133] herewith with these minor changes. Support for the changes can be found in the drawings as originally presented, and applicants submit that no new matter is presented. Applicants thus respectfully request that the amendments to paragraph [00133] be entered.

The new drawings are presented on Replacement Sheets 1-5 submitted herewith. A single change has been made to Figure 6, where the old reference numeral "70b" appearing at the right tip of the device has been corrected to now be -- 70a' -- in accordance with the amendments made to the specification at paragraph [00133]. Otherwise, the replacement drawings are merely formal versions of the drawings originally presented with the application. Applicants submit that the new drawings are in conformance with 37 C.F.R. §1.84, and do not add new subject matter. Applicants thus respectfully request that the new drawings be entered into the application.

The Drawing Objections

The drawings were objected to under 37 C.F.R. §1.83(a) as failing to show every feature of the intention as specified in the claims. In particular, the Office has objected that the two outlets recited in claim 17, and the two lumen recited in claim 18 must be shown in the drawings, or these features must be canceled from the claims, on the basis that "it is not clear where the two outlets or lumen are located." Corrected drawing sheets were required.

Applicants have submitted with this response a drawing amendment including a replacement for all of the originally filed drawings. However, applicants have not amended Figures 8A and 8B as requested by the Office. In this regard, applicants submit that the requirement of Section 1.83(a) has been met, since Figures 1-8 show all that is required for a proper understanding of the invention as claimed. The single outlet (24) at the termination of the lumen is merely indicative of a device containing one or more lumen and thus outlets, and the skilled artisan, when reading the claims and specification while viewing the drawings, will be able to understand that simple partitioning or duplication of the exemplified structure found in any one of Figures 1-8 provides a multiple lumen/outlet configuration. Applicants submit that there is nothing further required for a proper understanding of the claims as currently recited, and thus respectfully traverse the objection to the drawings. Reconsideration and withdrawal of the objection to the drawings under 37 C.F.R. §1.83(a) is thus respectfully requested.

The Rejection under 35 U.S.C. §102

Claims 1, 2, 4, 6-13, 18-20, 22, 24 and 29 stand rejected under 35 U.S.C. §102(b) as unpatentable over Wolinsky. In particular, the Office has equated the balloon catheter described in Wolinsky with the devices and drug delivery systems recited in applicants' claims. In this regard, the balloon portion of the Wolinsky device has been compared to applicants' recited diffuser elements, and the body of the Wolinsky catheter has been compared to applicants' recited elongate device body. The Office asserts "the [Wolinsky] device is capable of providing for dilution of a drug since, for example, if fluid pressure from the source of medicine is discontinued, some fluid from the patient's

body may enter element 16 [the balloon]." Office Action at page 3. Applicants respectfully traverse the rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The basis on which anticipation is measured is whether or not the prior disclosure is an "enabled disclosure" and this is particularly important when a theory of inherency is being used, as is the case in the instant rejection. *In re Samour*, 197 USPQ 1 (CCPA 1978). The Office's theory is that the balloon portion of the Wolinsky device could possibly inherently act as a diffuser element, where the Office suggests that possibly some fluid from the patient's body could enter the balloon upon deflation, that there would be drug present in the deflated balloon, and that the drug would then be diluted within the deflated balloon. The Office's theory is not sufficient under a Section 102 inherency rejection, since it is clearly the Office's burden to provide extrinsic evidence that the descriptive matter missing from Wolinsky is necessarily present in the Wolinsky device, that is, the balloon would necessarily act in this manner, and further that this feature would be recognized by persons of ordinary skill. *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

The Wolinsky balloon catheter device is configured as a catheter with a balloon over its distal tip. The balloon is formed from a substantially inelastic material (Wolinsky, col. 3, lines 47-60), and has "minute" holes of about 25 microns in diameter in the material (Wolinsky, col. 4, lines 1-11). The device is operated under very low pressure (2-5 atm) to provide a maximum flow rate of about 2 to 12 cc per minute, which is referred to as "weeping in nature" (Wolinsky, col. 4, lines 19-36). The material is purposefully inelastic so that the balloon does not over-inflate, rather the balloon will merely expand only in response to a fluid medicament being forced into the balloon under the 2-5 atm operating pressures. The tolerances of the balloon with respect to the body lumen in which it is placed are extremely small, and it is necessary that the device is aspirated in order to return the device to its starting diameter so that it may be withdrawn from the body lumen (Wolinsky, col. 4, lines 37-45).

Accordingly, operation of the Wolinsky device actually precludes the device from behaving in the manner that the Office has suggested. The minute holes only allow passage of a fluid medicament from within the device when maintained under pressure. There is no possibility that water or other fluids from the patient's lumen will flow into the device since it is so difficult to force the medicament through the minute holes in the balloon that body fluids cannot passively enter into the balloon. Deflation (e.g., discontinuation of the step of forcing pressure through the device) is clearly not sufficient to allow fluids to passively travel through the minute (25 micron) holes since it requires at least 2 atm of pressure just to move drug fluids through those same holes, in the opposite direction. Finally, aspiration of the device merely pulls undelivered drug from the balloon and back into the catheter, thereby decreasing the overall diameter of the device slightly to facilitate removal. In this regard, the undelivered drug is not diluted since no fluids have been able to pass in the reverse direction through the Wolinsky device balloon holes. In fact, if aspiration were sufficient to draw fluids into the device, this would frustrate the basic operation of the Wolinsky catheter, since the drug just delivered would be sucked back into the device. If a theory of inherency requires that the device is rendered unsatisfactory for its intended purpose (i.e., the Wolinsky device would have to remove delivered drug) then that theory cannot stand.

Applicants' claims all require that the recited devices (and the systems including such devices) include a diffuser element that provides for dilution of a drug within a defined diffusion space. The Wolinsky balloon catheter does not have such an element. In addition, the Office's assertion that the Wolinsky device would inherently have such an element is incorrect, since a proper reading of Wolinsky reveals that no fluids could enter the balloon as suggested by the Office and further, as applicants have demonstrated, the Office's proposed inherent feature would in effect render the balloon catheter unsatisfactory for its intended purpose. For this reason, the Wolinsky device would not necessarily act in the manner suggested by the Office (as required under §102), and this feature would never be recognized by persons of ordinary skill in the art. For all of these reasons, then, the rejection of claims 1, 2, 4, 6-13, 18-20, 22, 24 and 29 under 35 U.S.C.

§102(b) over Wolinsky is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

The Rejections under 35 U.S.C. §103

Claim 30 stands rejected under 35 U.S.C. §103(a) as obvious over Wolinsky. In particular, the Office asserts "Wolinsky discloses the invention as substantially claimed." However, the Office acknowledges that "Wolinsky does not teach ... the diffuser element has a Diffusion Coefficient value in the range between 4.1 X 10^{-6} to 3.3 X 10^{-5} μg/cm/sec." Office Action at page 6. However, the Office concludes "it would have been obvious to form the diffuser element [to have the Diffusion Coefficient] as claimed since Wolinsky teaches medication may have viscosity and flow characteristics that might require modifications to the holes." Applicants respectfully traverse for the following reasons.

When considering the patentability of claims under Section 103, the following tenets of patent law must be adhered to: (a) the claimed invention must be considered as a whole; (b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (c) the references must be viewed with the benefit of impermissible hindsight vision afforded by the claimed invention; and (c) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). It is clear that once these tenets are applied to the instant rejection, the rejection cannot stand.

As demonstrated above, the Office's theory that the Wolinsky balloon could serve as a diffuser element is incorrect. When Wolinsky is considered as a whole, it is clear that the operation that the Office has suggested is neither desirable nor obvious. In fact, the operation that the Office has suggested would render the Wolinksy device unsuitable for its intended purpose. Claim 30 requires a diffuser element. Wolinsky does no have such an element. The Office's proposal that a skilled artisan would intentionally modify the minute holes in the Wolinsky balloon so as to facilitate in-flow of fluids is clearly incorrect. Modification of the Wolinsky device in this way would destroy its entire

purpose, that is, to deliver drugs into a tight space defined by a lumen wall and a slightly expanded balloon surface under pressure. Accordingly, applicants' recited device cannot have been obvious over Wolinsky under any reasonable theory. Thus, when Wolinsky is considered as a whole, it is clear that it fails to teach or even suggest the desirability and thus the obviousness of making the device recited by applicants' claim.

Accordingly, applicants submit that the rejection of claim 30 under 35 U.S.C. §103(a) is improper. Reconsideration and withdrawal of the rejection is earnestly solicited.

Claim 21 stands rejected under 35 U.S.C. §103(a) as obvious over Wolinsky in view of Aoki. In particular, the Office asserts "Wolinsky discloses the invention substantially as claimed ... however Wolinsky does not disclose that the catheter contains Baclofen." Office Action at page 6. The Office then uses Aoki to provide the missing disclosure. Applicants respectfully traverse for the following reasons.

As demonstrated above, the primary reference to Wolinsky fails to teach or suggest applicants' recited devices. The inclusion of the Aoki disclosure fails to provide the missing teaching. Accordingly, the combination suggested by the Office clearly fails to teach or suggest the device recited in claim 21.

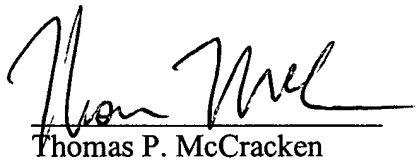
When Wolinsky and Aoki are considered as a whole for what they fairly teach the skilled artisan, it is clear that the Office's proposed combination does not render applicants' claims obvious. Accordingly, applicants submit that the rejection of claim 21 under 35 U.S.C. §103(a) is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

CONCLUSION

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus respectfully requested. In addition, if the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4915.

The fees for a one-month extension of time have been included with this communication, and no further fees are deemed necessary. However, if the Commissioner determines that additional fees are indeed necessary, or that no fees are due, the Commissioner is hereby authorized to charge any additional fees associated with this communication, or refund any inappropriate fees to Deposit Account No. **50-1953.**

Respectfully submitted,



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Thomas P. McCracken
Registration No. 38,548

For and on behalf of
DURECT CORPORATION
10240 Bubb Road
Cupertino, CA 95014
Phone: (408) 777-4915
Fax: (408) 777-3577